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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on Draft National Action Plan for Adverse Drug Event Prevention

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: The Office of Disease Prevention and Health Promotion is soliciting public comment on the draft National Action Plan for Adverse Drug Event Prevention.

DATES: Comments on the draft National Action Plan for Adverse Drug Event Prevention must be received no later than 5 p.m. on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].** This document provides an overview of current federal efforts to support surveillance, prevention, research, and the use of policy levers to reduce adverse drug events across the United States. The draft Action Plan reflects the work of many offices across the Department of Health and Human Services, Department of Defense, Department of Justice, and

Department of Veterans Affairs. The draft Action Plan also reflects input from national experts.

ADDRESSES: The draft National Action Plan for the Prevention of Adverse Drug Events is available at: http://www.hhs.gov/ash/initiatives/ade/ade-action-plan.pdf. Comments are preferred electronically and may be addressed to ADE@hhs.gov. Please use the title "Draft National ADE Action Plan" when sending comments electronically. Written responses should be addressed to the Department of Health and Human Services, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite LL100, Rockville MD 20852, Attention: Draft National ADE Action Plan.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION

I. Background

Adverse drug events (ADEs) have been defined by the Institute of Medicine as "an injury resulting from medical intervention related to a drug." This broad term encompasses harms that occur during medical care that are directly caused by the drug and can include,

but are not limited to, medication errors, adverse drug reactions, allergic reactions, and overdoses. ADEs can occur in any health care setting, including both inpatient and outpatient settings and even more likely to occur during patient transitions from one health care setting to another. ADEs are the single largest contributor to hospital-related complications within hospitals and account for over 3.5 million physician office visits, approximately 1 million emergency department (ED) visits, and an estimated 125,000 hospital admissions every year.

For these reasons, the reduction of ADEs is a top priority for the Department of Health and Human Services (HHS). Multiple Operating and Staff Divisions within HHS have been working to reduce the incidence and prevalence of adverse drug events for years. To further these efforts, in 2012, a Cross-Federal Steering Committee for Adverse Drug Event Prevention was established. The Steering Committee was charged with developing a comprehensive strategy to significantly reduce adverse drug events within the three drug classes which account for a significant proportion of all ADEs: anticoagulants, diabetes agents, and opioids. The draft Action Plan focuses on four main opportunities for federal engagement: surveillance, prevention, incentives and oversight, and research.

The draft Action Plan identifies current federal activity across both inpatient and outpatient settings, as well as transitions of care, that are related to these four opportunities, with a focus on the three drug classes associated with high levels of harm. It also highlights opportunities to advance these efforts through cross-federal partnerships and coordinated resources.

The release of the plan is only the beginning of a coordinated process that will result in stakeholders who are more engaged, aware, and knowledgeable of issues regarding the safe use of prescribed medications to prevent ADEs. Although the initial phase of the Action Plan reflects primarily the efforts and resources of federal agencies, the draft Action Plan was developed with the expectation and understanding that outlining ADE prevention goals and, more importantly, actually achieving ADE reductions and improving patient safety can be considered neither complete nor feasible without further engagement of professional organizations representing medical, nursing, pharmacy, and other allied health professionals, academia, patient and consumer representatives, and other private sector stakeholders. For this reason, every opportunity to ensure that feedback of and engagement with these entities will be sought through the public release of the draft Action Plan. Through coordinated federal partnerships, as well as public and private sector collaborations and aligned approaches, we can improve the quality and safety of health care, reduce health care costs, and improve the health and quality of life of millions of people in the United States.

II. Information Request

The Office of Disease Prevention and Health Promotion, on behalf of the HHS Steering Committee for Adverse Drug Event Prevention, requests input on the revised draft National Action Plan for Adverse Drug Event Prevention.

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in reducing adverse drug events. Some examples of these organizations include, but are not limited to the following:

- Caregivers or health system providers (e.g., physicians, physician assistants, nurses, pharmacists)
- Collaboratives and consortia
- Foundations
- Health care, professional, and educational organizations/societies
- Insurers and business groups
- Medicaid- and Medicare-related organizations
- Patients and their advocates
- Pharmaceutical Industry
- Prescription drug monitoring programs
- Public health organizations
- State and local public health agencies.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written materials submitted for consideration should not exceed 10 pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses, however, we request that comments are identified by section, subsection, and page number so they may be addressed accordingly. All comments received before the close

of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

DATED: August 28, 2013

Don Wright

Deputy Assistant Secretary for Health

Office of Disease Prevention and Health Promotion

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